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7590 10/03/2007 FRANK S. DiGIGLIO SCULLY, SCOTT, MURPHY & PRESSER			EXAMINER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

•		Application No		Applicant(s)		
Office Action Summary		10/028,346 A		ABDULLAH ET AL.		
		Examiner		Art Unit		
		Cynthia Collins		1638		
	The MAILING DATE of this communication app	pears on the cove	er sheet with the co	orrespondence addre	ess	
WHIC - Exter after - If NO - Failui Any r	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DA assions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period we tee to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS C 36(a). In no event, how will apply and will expire c, cause the application	OMMUNICATION wever, may a reply be time e SIX (6) MONTHS from to to become ABANDONED	I. ely filed the mailing date of this comm O (35 U.S.C. § 133).		
Status						
2a)□	Responsive to communication(s) filed on <u>Dece</u> This action is <b>FINAL</b> . 2b) This. Since this application is in condition for allowar closed in accordance with the practice under E	action is non-fir	ormal matters, pro		ierits is	
Dispositi	on of Claims					
5) ☐ 6) ☐ 7) ☐ 8) ☒ <b>Applicati</b> 9) ☐ 10) ☐	Claim(s) <u>1-69</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdray Claim(s) is/are allowed.  Claim(s) is/are rejected.  Claim(s) is/are objected to.  Claim(s) <u>1-69</u> are subject to restriction and/or expenses.  The specification is objected to by the Examine The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Examine The oath or declaration is objected to by the Examine Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Examine The oath or declaration is objected to by the Examine Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Examine The oath or declarat	wn from conside election requirer er. epted or b)  ot drawing(s) be hele tion is required if the	nent. Djected to by the E d in abeyance. See the drawing(s) is obje	e 37 CFR 1.85(a). ected to. See 37 CFR		
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Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
2) Notic 3) Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4)	Paper No(s)/Mail Da	te		

## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, 8-13, 15-23 and 25-26, drawn to an isolated nucleic acid molecule comprising SEQ ID NO:1, a genetic construct, a vector, a host cell, and a plant cell, classified in class 536, subclass 23.6, for example.
- II. Claims 1-5, 7-12, 14-22 and 24-26, drawn to an isolated nucleic acid molecule comprising SEQ ID NO:3, a genetic construct, a vector, a host cell, and a plant cell, classified in class 435, subclass 320.1, for example.
- III. Claims 27-31 and 33, drawn to an isolated polypeptide encoded by SEQ ID NO:1, classified in class 530, subclass 370, for example.
- IV. Claims 27-30 and 32-33, drawn to an isolated polypeptide encoded by SEQ IDNO:3, classified in class 530, subclass 370, for example.
- V. Claims 34-37 and 39-42, drawn to a method comprising introducing into a cell or tissue an expression vector an isolated nucleic acid molecule comprising SEQ ID NO:1, classified in class 435, subclass 468, for example.
- VI. Claims 34-36, 38-41 and 43, drawn to a method comprising introducing into a cell or tissue an expression vector an isolated nucleic acid molecule comprising SEQ
   ID NO:3, classified in class 435, subclass 471, for example.
- VII. Claim 44, drawn to a method comprising administering to a cell a recombinant polypeptide, classified in class 435, subclass 410, for example.

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- VIII. Claim 45-47, drawn to a method comprising immobilizing a sample containing RNA and contacting with a labeled nucleotide sequence as set forth in SEQ ID NO:1, classified in class 435, subclass 6, for example.
- IX. Claim 45-46 and 48, drawn to a method comprising immobilizing a sample containing RNA and contacting with a labeled nucleotide sequence as set forth in SEQ ID NO:3, classified in class 435, subclass 6, for example.
- X. Claims 49-52 and 54-55, drawn to an antibody to a polypeptide encoded by SEQID NO:1, classified in class 530, subclass 387.1, for example.
- XI. Claims 49-51 and 53-55, drawn to an antibody to a polypeptide encoded by SEQID NO:3, classified in class 530, subclass 387.1, for example.
- XII. Claims 56-60, drawn to a method comprising contacting a tissue or extract thereof to an antibody to a polypeptide encoded by SEQ ID NO:1, classified in class 435, subclass 7.1, for example.
- XIII. Claims 56-59 and 61, drawn to a method comprising contacting a tissue or extract thereof to an antibody to a polypeptide encoded by SEQ ID NO:3, classified in class 435, subclass 7.1, for example.
- XIV. Claims 62-63, drawn to a pharmaceutical composition, classified in class 514, subclass 2, for example.
- XV. Claims 64-67 and 69, drawn to a regenerated differentiated plant comprising a nucleic acid molecule of SEQ ID NO:1, classified in class 800, subclass 298, for example.

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XVI. Claims 64-66 and 68-69, drawn to a regenerated differentiated plant comprising a nucleic acid molecule of SEQ ID NO:3, classified in class 800, subclass 298, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II and inventions V-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the vector can be used in a materially different process of using that product, such as a method of producing vectors or a hybridization method.

Inventions I-II and inventions VIII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleotide sequence can be used in a materially different process of using that product, such as a method of constructing a genetic construct.

The isolated nucleic acid molecules of groups I-II are distinct from each other because they comprise structurally distinct nucleotide sequences. The isolated nucleic acid molecules of groups I-II are distinct from the methods of groups III-IV, VII and XII-XIII because the isolated

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nucleic acid molecules of groups I-II are not required to practice, or produced by, the methods of groups III-IV, VII and XII-XIII. The isolated nucleic acid molecules of groups I-II are distinct from the isolated polypeptides of groups III-IV, the antibodies of groups X and XI, the pharmaceutical composition of group XIV and the regenerated differentiated plants of groups XV and XVI because they differ from the isolated polypeptides, antibodies, pharmaceutical composition and plants in both classification and structure and/or composition. Accordingly the searches of groups I-II and groups III-IV, VII and X-XVI are not coextensive.

Inventions III-IV and invention VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the isolated polypeptides can be used in a materially different process of using that product, such as an immunization method.

The isolated polypeptides of groups III-IV are distinct from each other because they comprise structurally distinct amino acid sequences. The isolated polypeptides of groups III-IV are distinct from the methods of groups V-VI, VIII-IX and XII-XIII because the isolated polypeptides of groups III-IV are not required to practice, or produced by, the methods of groups V-VI, VIII-IX and XII-XIII. The isolated polypeptides of groups III-IV are distinct from the antibodies of groups X and XI, the pharmaceutical composition of group XIV and the regenerated differentiated plants of groups XV and XVI because they differ from the antibodies, pharmaceutical composition and plants in both classification and structure and/or composition. Accordingly the searches of groups III-IV and groups V-VI, VIII-XVI are not coextensive.

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The methods of groups V-VI are distinct from each other because they require the use of structurally different expression vectors. The methods of groups V-VI are distinct from the methods of groups VII-IX and XII-XIII because they require different materials and method steps. The methods of groups V-VI are distinct from the products of groups X-XI and XIV-XVI because the products of groups X-XI and XIV-XVI are not required to practice, or produced by, the methods of groups V-VI. Accordingly the searches of groups V-VI and groups VII-XVI are not coextensive.

The method of group VII is distinct from the methods of groups VIII-IX and XII-XIII because it requires different materials and method steps. The method of group VII is distinct from the products of groups X-XI and XIV-XVI because the products of groups X-XI and XIV-XVI are not required to practice, or produced by, the method of group VII. Accordingly the searches of group VII and groups VIII-XVI are not coextensive.

The methods of groups VIII and IX are distinct from each other because they require the use of structurally different nucleotide sequences. The methods of groups VIII and IX are distinct from the methods of groups XII-XIII because they require different materials and method steps. The methods of groups VIII and IX are distinct from the products of groups X-XI and XIV-XVI because the products of groups X-XI and XIV-XVI are not required to practice, or produced by, the methods of groups VIII and IX. Accordingly the searches of groups VIII and IX and groups X-XVI are not coextensive.

Inventions X-XI and inventions XII-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

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product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibodies can be used in a materially different process of using that product, such as immunolocalization or immunoprecipitation.

The antibodies of groups X and XI are distinct from each other because they are specific for structurally different proteins. The antibodies of groups X and XI are distinct from the pharmaceutical composition of group XIV and the regenerated differentiated plants of groups XV and XVI because they differ from the pharmaceutical composition and plants in both classification and composition. Accordingly the searches of groups X and XI and groups XIV-XVI are not coextensive.

The methods of groups XII and XIII are distinct from each other because they require the use of antibodies that are specific for structurally different proteins. The methods of groups XII and XIII are distinct from the products of groups XIV-XVI because the products of groups XIV-XVI are not required to practice, or produced by, the methods of groups XII and XIII.

Accordingly the searches of groups XII and XIII and groups XIV-XVI are not coextensive.

The pharmaceutical composition of group XIV is distinct from the regenerated differentiated plants of groups XV and XVI because it differs from the plants in both classification and composition. Accordingly the searches of group XIV and groups XV and XVI are not coextensive.

The regenerated differentiated plants of groups XV and XVI are distinct from each other because they comprise structurally distinct nucleic acid molecules requiring separate areas of search.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** 

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Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include

(i) an election of an invention to be examined even though the requirement may be traversed

(37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically

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point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins
Primary Examiner

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CC